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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,108	04/06/2000	Kenneth Eliot Sherman		7634

7590                    03/29/2002

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EXAMINER

WORTMAN, DONNA C

ART UNIT                PAPER NUMBER

1648

DATE MAILED: 03/29/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/544,108	SHERMAN, KENNETH ELIOT
	<b>Examiner</b>	<b>Art Unit</b>
	Donna C. Wortman, Ph.D.	1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 January 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,3-8,10-17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 1 and 3-6 is/are allowed.
- 6) Claim(s) 7,8,10-17 and 19-24 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Claims 2, 9, and 18 were canceled and claims 1, 3-8, 10, 11, 13, 16, 21, 22, and 24 were amended in Paper No. 4. Claims 1, 3-8, 10-17, and 19-24 are pending and under examination.

With respect to the continuing status of the application, Applicant has expressed the intention to update/clarify the continuing information as necessary at a future time.

New ground of rejection necessitated by amendment

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 as presented in Paper No. 4 are indefinite and believed to contain an error because each depends directly or ultimately from claim 7, which is drawn to a composition, but each recites "The method of ...". It is also noted that neither the clean copy nor the marked-up copy of claims 10 and 11 corresponds to claims 10 and 11 as originally filed. For the purposes of this examination, claims 10 and 11 are still treated as being drawn to a composition since it is believed that that is the intended subject matter.

New ground of rejection not necessitated by amendment

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 8, 10-17, and 19-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7-24 of copending Application No. 09/544109. Although the conflicting claims are not identical, they are not patentably distinct from each other because, except for the fact that instant claims 7 and 16 are now limited to a composition comprising  $\alpha$ -interferon while the independent claims of 09/544109 recite interferon more broadly, and the formulations of instant claims 16-24 have a different intended use (*viz.* the treatment of hepatitis C) from the intended use of claims 16-24 of 09/544109 (the treatment of hepatitis C), the cited claims of the two applications are drawn to the same subject matter. Intended use of a formulation is given no patentable weight since the compositions are the same.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Rejections maintained

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 12-14, 16, 17 and 21 are rejected under 35 U.S.C. 102(b) as anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Huang et al. for reasons of record in rejecting claims 7-9, 12-14, 16-18, and 21 in the previous Office action.

Claims 10, 11, 15, 19, 20, and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. in view of Hoofnagle et al., U.S. Patent 4,079,127 to Goldstein et al., and U.S. Patent No. 4,353,821 to Birr et al. for the reasons made of record in the previous Office action.

Applicant has argued that none of the references disclose the comparable efficacy of interferon and thymosin at lower doses than interferon alone, that Huang teaches treatment of hepatitis B and not treatment of hepatitis C; that one would not be lead to treat hepatitis C in the same way as hepatitis B because "For hepatitis C, the injury is mostly caused by the virus itself. For hepatitis B, the injury is caused by the immunologic response to the virus." Applicant has argued that Hoofnagle, Goldstein, and Burr do not teach the claimed hepatitis C treatment method.

Applicant's arguments have been considered but not found persuasive. It is agreed that the prior art does not teach the claimed treatment of hepatitis C with a combination of interferon and thymosin; the treatment claims were not and are not

subject to an art rejection. Claims 7, 8, 10-17, and 19-24 are drawn to compositions which are the same as, or obvious over, the composition of Huang for reasons of record and regardless of whether they are intended for use in treatment of hepatitis B, hepatitis C, or in any treatment method. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Huang teaches the combination of interferon and thymosin in a pharmaceutical composition. Hoofnagle, Goldstein, and Burr teach various aspects of interferons and thymosins and were cited for those teachings.

The factual basis for Applicant's assertion that the pathologic effect of hepatitis C is direct rather than immune-mediated is not understood. The state of the art at a time well after Applicant's invention was made indicates that the cause of the liver injury in hepatitis C is not certainly known. See, e.g., Rodriguez-Inigo et al., American Journal of Pathology 154:1877-1881, 1999 (cited on PTO 892, attached), in the Abstract: "It has

not been completely elucidated whether the liver injury induced by the hepatitis C virus (HCV) is due to direct cytopathic damage or to an immune-mediated response against HCV-infected hepatocytes." And, "... we have shown ... that the liver injury in chronic HCV infection is not directly related to either the number of infected hepatocytes or the serum HCV RNA concentration." Further, Applicant's arguments directed toward the types of treatment taught in the prior art are not seen to be particularly relevant to the rejection of composition claims, where intended use does not give rise to a structural difference. No arguments are directed to the compositions *per se*.

Claims 1 and 3-6 are allowed.

Because this action contains a new ground of rejection not necessitated by amendment, it is made non-final. Any inconvenience is regretted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Donna C. Wortman, Ph.D.

Primary Examiner

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dcw  
March 28, 2002